

March 17, 2004

MEMORANDUM

SUBJECT: EPA Risk Assessment Principles and Practices

FROM: Paul Gilman /SIGNED/
EPA Science Advisor

TO: Assistant Administrators
Regional Administrators
Deputy Regional Administrators
General Council
Deputy Assistant Administrators

The document, *An Examination of EPA Risk Assessment Principles and Practices*, represents an effort by the Environmental Protection Agency (EPA) to examine how risk assessment is conducted at the Agency (available at www.epa.gov/osa). The EPA Risk Assessment Task Force, a group of risk assessment professionals from across the Agency, was assembled to perform this examination. The document is an EPA **Staff Paper** which presents the perspectives of EPA risk assessors on how they understand risk assessment to be conducted at the Agency. Further, it presents staff recommendations for EPA and interested stakeholders to consider for how EPA can move forward with strengthening and, where appropriate, improving its risk assessment practices. This staff paper does not represent official EPA policy.

Stephen Johnson, Acting Deputy Administrator, Jessica Furey, AA Office of Policy, Economics, and Innovation, and I requested this report to further the discussion and examination of some broad questions about risk assessment. The contents of this staff paper are, in large part, presented in response to public comments submitted to the Office of Management and Budget (OMB) on EPA's risk assessment practices¹. Several comments highlighted concerns that EPA risk assessments are overly conservative and lacking in transparency. Other comments suggested that EPA's risk assessments are appropriately conservative — or in fact are insufficiently protective of public health — and noted that conservative defaults provide an incentive for generation of data to address uncertainties. While this report is not explicitly a “response to comments” document, the comments to OMB were used to suggest practices that

¹ In a February 3, 2003, Federal Register notice, the Office of Management and Budget requested public comment on “ways in which ‘precaution’ is embedded in current risk assessment procedures through ‘conservative’ assumptions in estimation of risk” and “Examples of approaches in human and ecological risk assessment...which appear unbalanced.”

the staff paper could address.

The Task Force's review is considered supplementary to other activities, such as revisions to EPA's risk assessment guidelines. Instead of addressing the specific issues targeted in other activities, the Task Force was charged with taking a broader look across EPA's risk assessment principles and practices, and with considering several issues as they relate to EPA risk assessment in general. Among the latter issues are questions such as:

- a) Is science policy mixed into the risk assessment process or not?
- b) Are EPA risk assessments sufficiently transparent in dealing with uncertainty and variability as well as identifying default assumptions when used in risk assessments?
- c) When data are not available, are the utilized default assumptions applied in such a way that the resulting risk estimates are reasonable and not unrealistic overstatements of risk?
- d) Are there characteristics of risk assessment that may result in risk underestimation that EPA should be addressing?

Further, the Task Force developed a set of recommendations based on its review. Some of the recommendations focus on increasing the certainty and confidence in EPA risk assessments, including development of more specific data relevant to a decision and ensuring that defaults that are invoked are themselves scientifically supported. Other recommendations encourage greater transparency and clarity in EPA risk assessment practices and the risk management process, such as greater use of planning and scoping and close attention to our existing guidance (e.g., Risk Characterization Policy and Handbook). Some specific recommendations include greater use of probabilistic analyses where appropriate (and development of these techniques where EPA has not traditionally used them), greater cooperation with EPA partners in risk assessment (e.g., states, foreign governments, affected stakeholders), and a constant vigilance to our peer review efforts. These recommendations will be critical in helping EPA update its agenda for further development of risk assessment practices. They will also be critical in augmenting key current activities, such as the completion of the cancer risk assessment guidelines revisions and the harmonization of human health risk assessment approaches.

Most important for the near future, this staff paper will serve as a vehicle for opening up a broader dialogue among EPA staff, EPA managers, and external parties about the practice of risk assessment at EPA. Several activities may take place as a part of this dialogue, including possible workshops with EPA's Science Advisory Board or other external groups, such as the National Academy of Sciences, on promising areas for further development of EPA risk

assessment practices. Also, meetings with states, non-governmental organizations, tribal groups, professional societies and other interested parties to seek their input and suggestions can be

sought. This staff paper represents the first step in a multi-step process geared towards advancing risk assessment principles and practices at EPA. Newer and better approaches for risk assessment may emerge as the dialogue proceeds.

cc: Science Policy Council